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September 23, 2009

Susan Lessard, Chair
c/o Terry Hanson
Board of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017

Re: *United States Surgical Corporation and Mallinckrodt LLC*

**Commissioner's Response to Mallinckrodt's Position on Burdens of Proof
and Scope of the Record**

Dear Ms. Lessard:

The Maine Department of Environmental Protection, by and through its counsel, the Maine Attorney General's Office, files the enclosed Commissioner's Response to Mallinckrodt's Position on Burdens of Proof and Scope of the Record for the Board's consideration.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter B. LaFond".

Peter B. LaFond
Assistant Attorney General

Enclosure

cc: Service List

Board of Environmental Protection Service List (07-08-09)
Mallinckrodt / US Surgical: Designation / Compliance Order

**Official Copy for Filings (by 4:00 p.m.) to
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Board of Environmental Protection Service List (07-08-09)
Mallinckrodt / US Surgical: Designation / Compliance Order

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**STATE OF MAINE
BOARD OF ENVIRONMENTAL PROTECTION**

UNITED STATES SURGICAL)	
CORPORATION and)	
MALLINCKRODT LLC)	
)	
CONCERNING A CHLOR-ALKALI)	COMMISSIONER'S RESPONSE
MANUFACTURING FACILITY IN)	TO MALLINCKRODT'S POSITION
ORRINGTON, PENOBSCOT COUNTY,)	ON BURDENS OF PROOF AND
MAINE)	SCOPE OF THE RECORD
)	
PROCEEDING UNDER 38 M.R.S.)	
§ 1365, UNCONTROLLED HAZARDOUS)	
SUBSTANCE SITES LAW)	

Mallinckrodt attempts to (1) artificially raise the burden of proof for the Commissioner and (2) limit evidence that the Commissioner can present at the hearing, while simultaneously arguing there should be no limit on the evidence it presents.¹ Not unsurprisingly, Mallinckrodt has found no legal or logical support for such arguments. If Mallinckrodt's arguments were to prevail, an unworkable procedural miasma would be created in which the Board would apply different evidentiary rules to different parties. Rather, the Board Chair should follow the language of the appeal provision of the Maine Uncontrolled Hazardous Substance Sites law ("Uncontrolled Sites Law"), 38 M.R.S. § 1365(4), which unequivocally establishes that the Commissioner must "first establish the basis for the Order and for naming the person to whom the order is directed." After that, the "burden of going forward then shifts to the person appealing." Thus, Mallinckrodt has the opportunity to produce its own evidence, or simply present argument based on that evidence produced by the Commissioner. The burden of persuasion, as with all appeals, is borne by the appellant Mallinckrodt.

¹ Mallinckrodt has the temerity to argue that the Commissioner's evidence is "limited" while it can present "all of the evidence" it wants. *See* Mallinckrodt Memorandum, p. 1.

I. The Commissioner Bears the Burden of Production, and Mallinckrodt Bears the Burden of Persuasion.

The relative burdens of the parties in this proceeding are addressed in the governing statute and therefore are not subject to serious dispute. The Commissioner bears the initial burden for “establish[ing] the basis for the order and for naming the person to whom the order is directed.” 38 M.R.S. § 1365(4). This initial burden is properly understood as a burden of production, which simply means the Commissioner has the burden to produce evidence that establishes the *basis* for the order, nothing more and nothing less. Mallinckrodt’s self-serving and vaguely referenced argument to the contrary is transparent. Mallinckrodt argues “the Commissioner has the initial burden of going forward to prove the basis for and necessity of each and every component of its November 24, 2008 Order.” Mallinckrodt Memorandum, p. 1 (emphasis added). The Uncontrolled Sites Law says nothing about “components” and the term is so vague it is guaranteed to create confusion. The Board will hear evidence from witnesses on both sides and arrive at a conclusion. There is no precise road map for how the Board will make its decision, just as a court must apply statutory language to facts.

Once the Commissioner produces the evidence that establishes the basis for the Order, then the burden shifts to Mallinckrodt “to demonstrate, based upon a preponderance of the evidence, that the order should be modified or rescinded.” 38 M.R.S. § 1365(4). Under the statute, therefore, Mallinckrodt has the burden of persuasion.² The burden of *persuasion* simply means Mallinckrodt has the burden to persuade the Board that the Order should be modified or rescinded. The statute’s assignment of the burden of persuasion to Mallinckrodt is consistent

² The statute’s assignment of the burden of persuasion to Mallinckrodt is supported by the placement of the “preponderance of the evidence” standard of proof in the sentence describing the appellant’s burden. No standard of proof is assigned to the Commissioner.

with its status as the Appellant in this appeal proceeding, since appellants inherently bear the burden of persuading the reviewing body that the decision below is flawed.³

II. The Record of this Proceeding Should Not Be Limited to Evidence That Existed at the Time the Order was Issued.

Mallinckrodt argues that the Board may only consider evidence in the Department's files at the time the Commissioner issued the Order in determining whether there is a basis for the Order. Mallinckrodt Memorandum, pp. 4-5, but places no limit on the evidence it can present. This transparent and baseless strategic maneuver should be dismissed.⁴ Mallinckrodt insists on this artificial distinction despite the Board's ruling that the standard of review is *de novo*.⁵ For the reasons set forth below, this position is inconsistent with the statutory provisions governing this proceeding, and is inherently in conflict with the purpose and effect of holding an adjudicatory hearing.

³ Although Mallinckrodt attempts to impose the "burden to persuade" on the Commissioner (*See* Mallinckrodt Memorandum, p. 4, fn. 4) Mallinckrodt admits that it must "prove, based upon a preponderance of the evidence, that the Order should be modified or revoked" (*see* Mallinckrodt Memorandum, p. 4) and that it has the "burden . . . to demonstrate, based upon a preponderance of all of the evidence provided to the Board, that the Department did not have a basis for the Order, and/or that some or all of the requirements of the Order are not necessary, such that the order should be modified or rescinded." *See* Mallinckrodt Memorandum, p. 5. Mallinckrodt's own words thus show that it has the burden of persuasion under 38 M.R.S. § 1365(4).

⁴ Mallinckrodt also asserts that the Commissioner's Order "must be grounded in the eleven RCRA remedy selection criteria *See* Mallinckrodt Memorandum, p. 3. Of course, the Board has already ruled to the contrary, following a previous procedural objection filed by Mallinckrodt.

⁵ Having agreed on the record that the standard of review is *de novo* for all parties (*see* Seventh Procedural Order, paragraph 3), Mallinckrodt attempts to hedge its bet. Mallinckrodt now argues that "Mallinckrodt, *as the party seeking revocation or modification*, is entitled to a *de novo* review of the Order." (emphasis added) *See* Mallinckrodt Memorandum, p. 4. Of course, the agreement among the parties, memorialized in the Seventh Procedural Order, has no such qualifying language. The *de novo* standard applies to the proceeding itself, and not only to Mallinckrodt.

The Uncontrolled Sites Law at § 1365 requires that a hearing be held when a Commissioner's Order is appealed. If no hearing were required (as in the typical appeal of a DEP license decision) then the "record" could be "frozen." However, even in licensing decisions Maine law contemplates the presentation of relevant evidence following the decision. As set forth in 38 M.R.S. § 341-D(4)(A), the Board may allow the record of a licensing decision to be supplemented by the Board, *and a hearing may be held*. So, even in a license decision, additional evidence may be presented and the record is not always "frozen." Here, the statute requires a hearing, and the parties must both have an opportunity to present all the relevant evidence.

Since the Board will be holding an adjudicatory hearing, the record of the proceeding inevitably will contain extensive evidence in the form of testimony that did not exist at the time the Commissioner issued the Order. The Board will be reviewing the direct, pre-filed testimony of the parties' various witnesses, observing their cross examination at hearing, evaluating their credibility and assigning weight to their conclusions. It is reasonable to expect that this testimony will substantially affect the Board's ultimate decision. Yet none of this important evidence existed at the time the Order was issued.

It is no answer to suggest that Department staff should base their testimony only on the "record" as it existed on the day the Order was issued. Witnesses cannot realistically be expected to testify only as to a *status quo* that has long since passed. Their understanding of the issues and evidence will have been influenced by countless intervening factors that would be impossible to purge from their consciousness. Moreover, there is no reason, based either in due process considerations or governing statutes, for the Board to deprive itself of the latest and most fully informed opinions of these important witnesses.

Since all testimony presented to the Board will necessarily post-date issuance of the Order, and it is unworkable to limit such testimony to how things may have looked at that now-distant point, it makes no sense for the Board to impose such an artificial restriction on other forms of relevant evidence that may have come to light during this intervening period. To the extent Mallinckrodt has performed studies or conducted analyses since the Order was issued that it believes support its position on appeal, we expect it will bring those to the Board's attention, and the Commissioner will offer no objection to them just because they were developed after the fact. Similarly, if the Commissioner has relevant information that was not available at the time of the Order, it would make no sense to deprive the Board of such evidence. This rule should apply uniformly to all categories of evidence: testimony, including that of experts, analysis of data, and raw data itself. If Mallinckrodt is permitted to use such evidence, and it should be, then certainly the Commissioner must be permitted to do so as well. Basic notions of fair play require that any limitations on admissible evidence apply even-handedly to all parties. This is not to suggest that the Commissioner intends to stitch together a *post hoc* rationalization to support the Order, and in fact the Commissioner plans little reliance on such post-order information during direct testimony. However, the Board would not serve itself well by granting Mallinckrodt's request to bar the Commissioner from introducing any such evidence.

The fact that the Board can and should consider whatever evidence is available at the time of the hearing, as opposed to the day the Order was issued, is also consistent with its decision-making responsibility under the statute. The Board will not simply consider whether to uphold or rescind the Commissioner's Order, but instead must consider whether to "modify" it. 38 M.R.S. § 1365(4). It would defy common sense for the Board to decide upon modifications to the Order that could dramatically alter its effect while ignoring evidence simply because it came

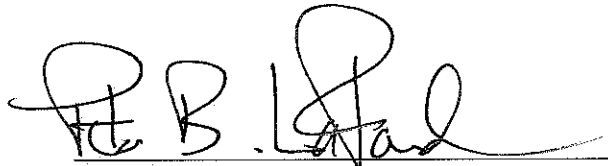
to light since the date the Order was issued. Significantly, there is nothing in the statutes governing this proceeding that requires or even suggests that the Board should screen the evidence that it receives at hearing in this way.

CONCLUSION

The Board should employ the burdens of proof as expressly set forth in the plain language of the Uncontrolled Sites Law, and reject Mallinckrodt's attempt to limit the evidence the Board should consider. Nothing indicates, much less compels, a contrary result.

Dated at Augusta, Maine, this 23rd day of September 2009.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter B. LaFond", written over a horizontal line.

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